IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA, *ex rel.* **AMANDA WU**	:	
Plaintiff,	:	**FILED UNDER SEAL**
v.	:	**CIVIL NO. GLR-11-1808**
ALERE SAN DIEGO, INC., *et al.*	:	
Defendants.	:	

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UNITED STATES' NOTICE OF INTERVENTION-IN-PART FOR PURPOSES OF EFFECTUATING SETTLEMENT AND DECLINATION-IN-PART

The United States, Relator, and Defendant have reached a settlement agreement to resolve the claims brought on behalf of the United States in this action. In light of this agreement, and for the purpose of effectuating and formalizing that resolution, pursuant to the False Claims Act, 31 U.S.C. §§ 3730(b)(2) and (4), the United States respectfully advises the Court of its decision to intervene in part for the purposes of settlement and to decline in part.

Specifically, the United States intervenes in this action with respect to civil claims predicated upon the following factual allegations (the "Covered Conduct):

> During the period January 1, 2006, through March 31, 2012, Alere SD developed, manufactured, and sold the Triage Devices for use in rapid point-of-care testing to aid in the diagnosis of certain diseases and conditions. The Triage Devices were used primarily at or near the site of patient care, including in the emergency department or patient bedside. The Triage Devices were used to support and aid the clinical decision making relating to patients suspected of acute coronary syndromes, heart failure, drug overdose, and other serious conditions where timely decisions are critical to ensuring proper patient care.

Certain Triage Devices were used in aid of diagnosis of cardiac conditions. Triage cardiac devices work by measuring the concentrations of cardiac enzymes or analytes that are recognized biochemical markers associated with cardiac injury ("cardiac markers"). In using these cardiac marker testing devices, clinicians collect a small sample of the patient's blood that is placed on the device, which is then placed into a meter that provides a measurement of the concentrations of the relevant cardiac markers to aid in diagnosing the patient.

Other Triage Devices were used for toxicology testing, allowing clinicians to test for the presence of certain metabolites of prescription and non-prescription drugs ("drug markers"). In using these toxicology testing devices, clinicians collect a urine sample that is placed on the device, which is then placed into a meter that provides a qualitative determination regarding the presence of the drug markers.

The United States alleges that the Triage Devices were marketed and sold with product inserts that made representations regarding the device specifications, including the coefficient of variation ("CV") for each cardiac marker or drug marker measured by the devices. The CV represents a measure of variation for a distribution of test results within a product lot. It is the ratio of the standard deviation to the statistical mean of the test results. With regard to the cardiac Triage Devices, each product insert denoted the relevant CV for each cardiac marker tested.

The United States contends that Alere SD manufactured and sold Triage Devices between January 1, 2006, and March 31, 2012, for which the actual device CV, including the CV at the most relevant level, differed materially from the CV representations contained on the product labeling and the 510(k) submissions, and were not compliant with then Current Good Manufacturing Practices. The United States contends that the disparity between the actual CV and the CV representations contained on the product labeling resulted in the certain devices having significantly decreased precision relative to the claims made in the package inserts. The United States contends that the decreased precision, in turn, had the potential to create false positives or false negatives that adversely affected clinical decision making.

The United States contends that Alere SD personnel were aware of this disparity and aware that it put the company at considerable regulatory and financial risk given the company's inability to set specifications correctly and the resulting potential for decreased precision when using the products. The United States alleges that Alere SD was also aware of customer complaints regarding tests that produced false positives and false negatives that could have been related to the disparity in CV and resulting decreased precision for certain cardiac Triage

> Devices. The United States contends that, despite customer complaints regarding false positives and false negatives, Alere failed to take appropriate corrective or preventive actions.
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> The U.S. Food and Drug Administration ("FDA") conducted inspections of Alere SD facilities in the spring of 2012, and the United States contends that FDA personnel identified (i) statistically significant disparities between the actual cardiac Triage Device CV specifications and the CV specifications marketed to clinicians on the product labeling; (ii) an unacceptably high degree of variability when conducting quality control testing of the cardiac Triage Devices; and (iii) changes to the manufacturing and release specifications for toxicology Triage Devices that resulted in the release to market of certain products lots containing products that potentially had significantly decreased precision.
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> On May 22, 2012, Alere SD sent an "Urgent Medical Device Recall" to its customers to notify them that the company was initiating a "voluntary recall" of certain lots of the Triage Devices. The notification explained that "these lots may have significantly decreased precision relative to the package insert, which could result in an increased frequency of false positive or false negative results." The company further advised that "there have been reports of patients receiving inappropriate clinical management which may have been due to such erroneous results." Customers were instructed to discontinue use of the affected products subject to the recall. On June 11, 2012, Alere SD sent a second "Urgent Medical Device Recall" to its customers to notify them that the "voluntary recall" of Triage Devices included additional product lots. A third recall letter was issued on June 12, 2012, expanding the recall to include several additional lots of Triage Devices.

The United States declines intervention with respect to all other claims alleged in this action apart from those based upon the Covered Conduct.

Under the terms of the settlement agreement among the parties, following Alere's payment of the federal settlement amount, the United States and the Relator will file a Notice of Dismissal with respect to all claims brought on behalf of the United States. Because the Relator and Alere have not resolved Relator's claims of attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) nor Relator's claims for retaliation under 31 U.S.C. § 3730(h) and pendant California state statutes,

these person claims of Relator will not be dismissed.

In light of the settlement agreement reached among the parties, the United States does not presently intend to file a complaint in intervention but reserves the right to seek leave to file such a complaint in the event that Alere does not pay the full settlement amount consistent with the terms of the settlement agreement.

Finally, the United States hereby requests that the Court unseal the Relator's First Amended Complaint, this Notice of Intervention for Purposes of Effectuating Settlement, and all subsequent filings following this Notice. The United States further requests that all other papers on file in this action remain under seal because in discussing the content and extent of the United States' investigation, such papers are provided by law to the Court alone for the sole purpose of evaluating whether the seal and the time for making an election to intervene should be extended.

A proposed order accompanies this Notice.

Respectfully submitted,

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By: _____

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CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of March 2018, a copy of the foregoing United States' Notice of Election to Intervene was mailed, postage prepaid to Counsel for Relators:

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